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No. 88-614

IN THE

Supreme Court Of The United States

OCTOBER TERM, 1988

9/1 KG CONTAINERS, MORE OR LESS,
OF AN ARTICLE OF DRUG FOR VETERINARY USE,
AND SCHUYLER LABORATORIES, INC.,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

PETITIONERS' REPLY BRIEF

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I. INTRODUCTION

The brief for the United States in Opposition ("Gov. Br.") must be read closely to find acknowledgment of the statutory theory upon which the government proposes to regulate the practice of medicine. Only on the fifth page does the brief recognize that the bulk drugs are for use in the veterinarian's treatment of animals. It is not easy to see that the government proposes to secure, through the Seventh Circuit decision, the novel authority to insert itself between each patient and practitioner to preclear every use of medicine by the practitioner.

The government never forthrightly acknowledges the mechanism it seeks to employ to regulate the bulk drugs. The sole reason that the bulk drugs are considered "new" by the Food and Drug Administration ("FDA"), and therefore the reason why they would require premarket approval, is the way that they are to be

used by veterinarians in their practices. FDA contends that each and every use of a medicine by a veterinarian is subject to the preclearance authority procedure established in the Federal Food, Drug, and Cosmetic Act ("Act") for "new" drugs.[1] In other words, it is not sufficient that bulk drugs used in medical practices be pure and of the proper strength. The government asserts that FDA must know about each use with each patient, and that the new drug approval process must be employed to approve each such use in advance. The government asserts nothing less than this, but declines to say so in its brief.

This theory, sustained by the Seventh Circuit[2] and rejected by the district court below[3] and the district court in *Algon*,[4] means that no medicine may be used by any veterinarian until and unless some commercial enterprise has seen fit to secure approval of a drug from FDA. The government's brief does not even acknowledge this. Beneath the recitations about the good purposes of the Act, the predictions of its demise and unsubstantiated threats to health unless the bulk drug regulation can be used as FDA proposes, the government is seeking a radical revision of the historical relationship between itself and the practice of medicine. Under this new scheme the decisions made in the doctor/patient relationship are subordinated to FDA. The district court saw this. The Seventh Circuit saw it too, but, looking past the legislative history of the Act and prior precedents, decided that the government should have control over how practitioners use medicines.

Perhaps the reticence of the government to describe the basis of its case and the implications of the Seventh Circuit's ruling derives from their conflict with the current regulatory system. The task of this reply then is to explore some remarkable omissions and obfuscations.

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[1] Gov. Br. at 4-5 (discussing 21 C.F.R. §201.122 (1988)).

[2] *United States v. 9/1 Kg Containers*, 854 F.2d 173, 179 (7th Cir. 1988), Appendix to Schuyler Petition ("App.") at 9a.

[3] *United States v. 9/1 Kg Containers*, 674 F. Supp. 1344, 1348-1349 (C.D. Ill. 1987), *rev'd*, 854 F.2d 173 (7th Cir. 1988), App. at 19a-20a.

[4] *United States v. Algon Chemical Inc.*, 689 F. Supp. 394, 399-400 (D.N.J. 1988), *appeal docketed*, No. 88-5478 (3d Cir. argued Jan. 9, 1988), App. at 42a-43a.

II. MEDICAL PRACTICE AND THE ACT CAN COEXIST

A. The Act Will Not Be Circumvented

Without saying exactly how, the government twice asserts that unless the agency can exert prior approval authority over each medicine used by practitioners, then the entire system of FDA approvals would collapse. Gov. Br. at 8 and 16. The government argues that without this power over all medicines, the system for regulating bulk drugs would be undermined, meaning that manufacturers will simply sell bulk products and stop making final dosage products. It should be a sufficient response to say that the basic regulatory system has continued in service for over fifty years since the passage of the Act without FDA asserting this new authority.

There is however another potent reason why the use of bulk drugs by practitioners to make their own medicines will not destroy the FDA's drug approval system. The reason is advertising. No one can deny the importance of advertising in the pharmaceutical business. FDA's regulations expressly recognize that bulk drugs, including drugs for prescription compounding, can be advertised and sold but that no therapeutic claims can be made for such bulk products. 21 C.F.R. §§202.1(e)(2)(ii) and (iii) (1988).[5] If any therapeutic claim is made for a bulk drug product, then that will make it subject to being considered "new" and prior agency approval of the product for that use would be required. Pharmaceutical houses are only too willing to be regulated and to pass products through the new drug clearance procedure in order to advertise their products for approved uses.

B. The Public Will Be Protected

Not only will the regulatory system not collapse, it can continue to function appropriately to protect the public health without giving FDA the power to practice medicine. The government says that nothing in the legislative history of the Act suggests that "misbranded or adulterated bulk drugs, or drugs that are deemed dangerous or ineffective by the FDA" may be shipped

[5] Section 202.1(e)(2)(iii), entitled "Advertisements of prescription-compounding drugs," again shows that FDA has in the past and currently recognizes the need for compounding of medicines.

"simply because the recipient is a veterinarian." Gov. Br. at 9. Petitioner, Schuyler Laboratories, Inc. ("Schuyler"), has never contended that the Act allowed such activity. The agency is now and always has been able to stop the shipment of any misbranded or adulterated drugs, and any drugs that it considers dangerous or ineffective.

If FDA considers any drug to be dangerous, either because of the harm it does or the harm it might do because it is ineffective, then it can stop any health care practitioner from receiving that drug. For example, the bulk drug regulation at issue here, 21 C.F.R. §201.122, does not exempt bulk drugs from Section 502(f)(2) of the Act, 21 U.S.C. §352(f)(2)(1982). Under that provision, the FDA could prevent a bulk drug from being shipped if its labeling did not provide adequate warnings against conditions in which its use "may be dangerous to health, or against unsafe dosage or methods or duration of administration or application ...."

Also, bulk drugs are not exempt from Section 502(j) of the Act, 21 U.S.C. §352(j) (1982), which deems a drug, including a bulk drug, to be misbranded if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." If the labeling said "for compounding by a veterinarian" and use by veterinarians were dangerous, as FDA asserts is the case with some drugs such as dimetridazole,[6] then FDA could of course intervene under the existing law. FDA could cause the seizure of the drugs, enjoin their shipment, or even prosecute persons responsible for such shipments. 21 U.S.C. §§331-334 (1982).

The law also requires that all drugs -- bulk or finished form, approved through the "new drug" process or unapproved -- be made under good manufacturing conditions, and that they be pure and of proper strength. 21 U.S.C. §351(a)(2)(B) (1982); 21 C.F.R. Part 211 (1988). Drugs that fail to meet such requirements, including bulk drugs, are legally adulterated. *Id.*

There is therefore no need for the government to extend its authority into the practice of medicine in order to protect the

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[6] Gov. Br. at 14 n.13.

public from unsafe medicine. FDA has ample regulatory powers to protect the public health without requiring prior approval of every use of a drug by a veterinarian.[7]

C. Public Health Requires That Practitioners Be Allowed To Treat Their Patients Without Federal Interference

The argument that the public safety requires that the government should be the referee to decide how the healing practitioners may treat each patient is empty, contradicted by the history of agency practice and inconsistent with the clearly expressed intent of Congress. As this Court stated in a different context in *Bowen v. American Hospital Association*, ____ U.S. ___, 106 S.Ct. 2101, 2121 (1986), "Congress has failed to indicate, either in the statute or in the legislative history, that it envisioned federal superintendence of treatment decisions traditionally entrusted to state governance." This conclusion applies with equal force here.

The falsity of the government's argument is made apparent by the uncontradicted statements of veterinarians who establish the harm to food animals if they cannot be treated until the pharmaceutical houses decide to gain FDA approval for the animals' afflictions.[8] The *amicus* briefs of the Humane Society of the United States and the American Food Animal Veterinary Medical Association eloquently describe the harm that will result if the Seventh Circuit's decision is sustained. The irrationality of the government's argument is made palpable by the admission of the head of FDA's Center for Veterinary Medicine that the agency's interpretation of the Act will force veterinarians to choose between adherence to professional ethics or exposure to criminal liability.[9]

The Seventh Circuit expressed considerable skepticism about the ability of physicians, veterinarians, and other medical professionals to employ drug therapy without a Washington guide.

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[7] The controls affecting veterinarians are described in Schuyler's Petition for Writ of Certiorari ("Schuyler Petition") at 29.

[8] This record was discussed in the Schuyler Petition at 6-7.

[9] Guest Deposition, Appellees' Supplemental Appendix filed in the Seventh Circuit (Appellees' App.) at 69-71.

This skepticism was not shared by the Congress, as the legislative history shows. Schuyler Petition at 8-18. Nor is this skepticism shared by FDA.[10] And other courts of appeals have observed the *necessity* for medical practitioners to use medicines in a manner not approved by FDA.[11] Further, the record in this case demonstrates that training to compound and use medicines is part of the routine professional training of veterinarians.[12] The Act contemplates that manufacturers of "new drugs" need prior approval for their products, but the Act does not equate that kind of business with the professional task of using medicines to treat patients.

III. UNAPPROVED USE VERSUS BULK DRUG USE

The government in many places refers to the distinction between the use of approved drugs for unapproved purposes and the use of bulk drugs, for which there is no approval. This is a distinction without a difference. It is important to repeat that drugs that have gone through the new drug approval process and those that have not are subject to FDA's requirements for good manufacturing, purity, strength, and proper labeling. Thus, the consequences of using drugs for "unapproved" uses are indistinguishable, except that pure bulk drugs are usually easier to use for compounding purposes because they do not have unwanted or difficult active or inactive components that finished drug products have blended in them.[13]

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[10] *See, e.g.*, Compliance Policy Guide 7132.06, "Hospital Pharmacies - Status as Drug Manufacturer," Exhibit K to Claimant's Memorandum in Opposition to Plaintiff's Motion for Summary Judgment and in Support of Claimant's Motion for Summary Judgment (where FDA states that hospital pharmacies may compound unapproved medications on a physician's order without obtaining clearance under the "new drug" provisions of the Act).

[11] *Grinspoon v. DEA*, 828 F.2d 881, 887 (1st Cir. 1987); *Chaney v. Heckler*, 718 F.2d 1174, 1180 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985).

[12] *See, e.g.*, Biehl Statement at ¶¶4-5, Appellees' App. at 20; Clack Statement at ¶¶3, 4, and 7, Appellees' App. at 22-24.

[13] Clack Statement at ¶9, Appellees' App. at 25; Skiles Statement at ¶7, Appellees' App. at 32. The government says FDA does not "usually" approve bulk drugs. Gov. Br. at 2. In fact, it never approves bulk drugs and has no procedure to do so; this means that no bulk drug, though pure and of proper strength, is ever "approved" through the new drug clearance procedure.

FDA has expressly recognized that the use of approved drugs in an unapproved manner is not regulated by the Act if done within the scope of a *physician's* practice. 37 Fed. Reg. 16,503 (1972); 52 Fed. Reg. 8798, 8803 (1987).[14] *See also, United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981), where the agency acknowledged the legality of such prescribing under the Act. FDA has not, however, attempted to explain how the use of a bulk chemical to treat patients is outside of the practice of medicine. The Seventh Circuit's opinion makes no distinction between the unapproved use of approved drugs and the use of bulk drugs, or the use of such drugs by one kind of practitioner or another.[15] According to the Seventh Circuit, the Act prohibits all licensed practitioners from using any drug for an unapproved purpose and thus empowers FDA to regulate the treatment decisions of all licensed practitioners. 854 F.2d at 176-177, App. at 5a.[16]

IV. THE CITED AUTHORITIES AND IGNORED PRECEDENTS DO NOT SUPPORT THE SEVENTH CIRCUIT'S DECISION

The authorities ignored by the government and even the authorities cited in its brief contradict the theory that the Act empowers FDA to preclear each and every use of a medicine by practitioners.

The Seventh Circuit and the government in its briefs below and here have paid little attention to the legislative history of the Act. Yet that history is clearly and totally contradictory to the

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[14] The government argued in the district court and in the court of appeals that the Act requires that veterinarians, but not other practitioners, use drugs only for their approved purposes. Plaintiff's Memorandum in Opposition to Claimant's Motion for Summary Judgment at 11-15; Reply Brief for the Appellant at 11-12. Thus, according to FDA, physicians when treating humans can use approved drugs for unapproved purposes, but veterinarians when treating animals cannot.

[15] The Seventh Circuit does, however, misread the agency's promise to consider regulatory action against veterinarians who use approved drugs in an unapproved manner as a "non-enforcement policy." *United States v. 9/1 Kg Containers*, 854 F.2d at 178, App. at 7a-8a; Schuyler Petition at 27.

[16] The Seventh Circuit ruling applies with equal force to the prescriptions compounded by pharmacists and physicians. Therefore, they would not be entitled to receive bulk drugs for compounding.

authority that they seek to give the government over the healing professions.

The most thorough, recent analysis of the legislative history appears in the court of appeals' opinion in *Chaney v. Heckler*, 718 F.2d 1174 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985). Schuyler has discussed this opinion in its petition. Schuyler Petition at 19-20. Ignoring the court of appeals' analysis at pp. 1179-1180, the government cites those pages for the proposition that "FDA had the authority to limit the uses that a physician could make of an approved drug." Gov. Br. at 17. Yet the ignored analysis recognized the "practice-of-medicine" exemption and provided a detailed explanation for doing so.[17]

This readily acknowledged exemption -- from the new drug approval process, not the Act itself -- is of course the very exemption that the Seventh Circuit found did not exist. It is therefore no wonder that the government deals with the *Chaney* decision by not addressing this vital component of it. Further, only by ignoring the *Chaney* analysis, the legislative history, and other decisions is it possible for the government to argue, as it has, that there is no split of authorities among the circuits. Gov. Br. at 16-17.[18]

The government also misstates the holding of *United States v. Rutherford*, 442 U.S. 544 (1979). Gov. Br. at 11. To say that the Court "held" that physicians might not obtain Laetrile for use in terminally ill patients without FDA's prior approval is to extend the holding into an area that the Court simply did not explore. The issue of the practice of medicine and its relationship to FDA's authority was not considered in the Court's opinion. The opinion and the arguments presented to the Court related to the applicability of a right of privacy to permit the patients to receive un-

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[17] The government also ignores the finding made by the court of appeals that "*(n)onmedical* use of lethal injections ... cannot fall within the 'practice-of-medicine' exemption ...." 718 F.2d at 1180. (Emphasis added.)

[18] The government's brief also distorts the precedent of *United States v. Evers*. The rationale of that case, and the recognition in it -- by the Fifth Circuit and the FDA -- that FDA is not empowered to regulate treatment decisions of practitioners, are in no wise diminished by the fact that the drug involved was "a prescription drug prescribed and dispensed by a licensed physician ...." Gov. Br. at 17.

approved drugs. The Court's rejection of that argument does not eradicate the "practice-of-medicine" exemption. Note, however, that the exemption would not prevent FDA from halting the shipment of quack remedies such as Laetrile to practitioners in bulk or finished form. 21 U.S.C. §§352(f)(2) and 352(j).

V. THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE VIRUS-SERUM-TOXIN ACT SHOULD BE INTERPRETED TOGETHER

The government dismisses the Virus-Serum-Toxin Act ("V-S-T Act"), saying that it "is an entirely separate law and supplies no assistance in interpreting the provisions of the FDCA [Federal Food, Drug, and Cosmetic Act]." Gov. Br. at 15. The V-S-T Act, which requires the prior federal approval of animal biologics, expressly exempts from such approval requirements biologics prepared by a veterinarian for use in his or her practice. 21 U.S.C. §154a(2) (Supp. IV 1987). The government's argument ignores several salient facts. First, animal biologics, whether subject to premarket approval or exempt from such requirement, are nevertheless "drugs" under the Federal Food, Drug, and Cosmetic Act and therefore subject to the adulteration and misbranding provisions of that Act. *Grand Laboratories, Inc. v. Harris*, 660 F.2d 1288 (8th Cir. 1981), *cert. denied*, 456 U.S. 927 (1982). Therefore, FDA can take enforcement action against a veterinarian who compounds an adulterated or misbranded biologic notwithstanding that the product is exempt from premarket approval.

Second, the Federal Food, Drug, and Cosmetic Act provides that it shall not be construed "as in any way affecting, modifying, repealing, or superseding the provisions of ... the virus, serum, toxin, and analogous products provisions, applicable to domestic animals ...." 21 U.S.C. §392(b)(1982). If the two statutes were "entirely separate" as the government contends, this provision would have been unnecessary.

Third, FDA's regulations expressly exempt from the approval requirements of Section 512 of the Act, 21 U.S.C. §360b, "[a]n animal drug produced and distributed in full conformance with the animal virus, serum, and toxin law ... and any regulations issued thereunder ...." 21 C.F.R. §510.4 (1988). The regulation

does not, however, exempt animal biologic drugs from other requirements of the Act.

Where two statutes deal with the same subject, as here, they should be interpreted together. Sutherland Stat. Const. §51.02 (4th Ed.). Where there are several possible interpretations of a statute, the one which produces a reasonable result is favored. *American Tobacco Co. v. Patterson*, 456 U.S. 63, 71 (1982). The result advocated by the government here is without question unreasonable. The government has not even attempted to explain what rationale or public policy supports its theory that Congress intended to exempt veterinarians from premarket approval when they compound their own biologic drugs, such as vaccines, but that Congress intended to require veterinarians to obtain federal approval to engage in the very same activity with non-biologic drugs. Rather the government makes the unconvincing argument that "Congress knows how to exempt veterinarians from premarketing approval requirements when it wishes to do so ...." Gov. Br. at 15.

VI. CONCLUSION

The conflict of the Seventh Circuit's decision with all preceding interpretations of the status of the healing professions under the Act warrants this Court's review. The Act is intended to protect the public by preventing unsafe drugs from reaching the market *and* allowing the medical practitioners to use their professional training to treat and help patients. The Seventh Circuit's decision disrupts the partnership between the healers and the regulator, and calls into question the legality of compounding by physicians and pharmacists as well as veterinarians, activities for which they all are licensed by their state governments. This raises an issue of vital significance to the public health.

Respectfully submitted,

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